

Plaintiff tries to avoid the *Daubert* “exacting standards of reliability” for expert testimony, *Weisgram v. Marley Co.*, 528 U.S. 440, 455 (2000), by repeatedly exaggerating the holdings from previous Aredia[®]/Zometa[®] cases, many of which have excluded the same testimony that Novartis Pharmaceuticals Corporation (“NPC”) seeks to exclude in this case, and asserting the inapplicable “law of the case” doctrine. But plaintiff has failed to establish that the particular opinions of Dr. Robert Marx addressed in NPC’s motion – that NPC engaged in “bad faith” conduct; his hindsight criticism of NPC’s clinical trial designs; that certain patients in the clinical trials for Zometa[®] and Aredia[®] had BIONJ; that dental treatment measures prevent BIONJ; commentary about adverse event reports that he has not reviewed; and his opinion about the biological mechanism by which bisphosphonates allegedly cause osteonecrosis of the jaw (“ONJ”) – are scientifically reliable and otherwise admissible.

I. Previous Courts In The Aredia[®]/Zometa[®] Litigation Have Limited The Scope Of Dr. Marx’s Testimony.

A. Dr. Marx’s opinions that NPC engaged in “bad faith” conduct and his speculation about NPC’s motives and intent are inadmissible.

Courts in the Aredia/Zometa litigation have repeatedly held that Dr. Marx’s opinions about a NPC’s alleged state of mind, intent, motives, or ethics are not proper subjects for expert testimony. *See, Deutsch v. Novartis Pharms. Corp.*, Nos. 09-CV-4677, 09-CV-4678, 2011 WL 790702, at *26-28 (E.D.N.Y. Mar. 8, 2011) (excluding Dr. Marx’s bad faith conduct testimony even if it is “rationally based on his perception of NPC’s conduct which he personally witnessed” (citation omitted)); *Hogan v. NPC*, 06 Civ. 0260 (BMC) (RER), Order (E.D.N.Y. April 24, 2011) at 7-8 (“*Hogan Order*”) (Exhibit 11 to NPC’s Opening Brief (ECF No. 33-11) (excluding Dr. Marx’s speculation about NPC’s intent, motives, and alleged bad faith conduct, ordering him to “keep his characterizations of defendant’s responses and opinion regarding its

conduct to himself,” and noting the court’s “concern that all of plaintiff’s experts, to some degree, are being proffered as ‘superlawyers’ to serve as scientifically informed advocates that plaintiff wants the jury to reach and which belong only in summation, not expert testimony”).

Indeed, Dr. Marx’s allegations that NPC engaged in bad faith and his speculation about NPC’s intent and motives even failed to satisfy the expert admissibility standard applied in New Jersey state courts, which is *more lenient* than the standards imposed by the Federal Rules of Evidence and *Daubert* in this case. *Bessemer v. Novartis Pharm. Corp.*, No. MID-L-1835-08-MT (N.J. Super. Ct. Law Div. Apr. 30, 2010) (“*Bessemer Opinion*”) (Exhibit 12 to NPC’s Opening Brief, ECF No. 33-12) (“Issues regarding state of mind, intent, motives, or ethics on the part of Defendant or any of NPC’s employees are not the proper subject of an expert opinion but, instead, are matters to be argued by counsel based on the evidence. Thus, any such testimony by Dr. Marx shall be excluded.”). Plaintiff has provided no valid reason for this Court to depart from these previous rulings.

Plaintiff contends that Dr. Marx should be able to testify as a fact witness about his experiences working with NPC and NPC’s employees. Pl’s Opp’n at 9. She agrees with NPC, however, that *the jury* can decide whether NPC was acting in bad faith, thereby admitting that Dr. Marx’s proffered expert testimony on NPC’s alleged bad faith will not assist the trier of fact. *See* Fed. R. Evid. 702. Dr. Marx’s bad faith opinions should be excluded based on plaintiff’s admissions.

Given her admission that the jury can determine whether NPC acted in bad faith without Dr. Marx’s alleged expert assistance, plaintiff argues for the admissibility of Dr. Marx’s opinions as mere fact testimony. Pl’s Opp’n at 9-10. The jury, however, will struggle to distinguish Dr. Marx’s “expert” opinions from his “fact” testimony. Any fact witness testimony he provides

will be colored by his expert status and prejudice NPC. *See generally United States v. Frazier*, 387 F.3d 1244, 1263 (11th Cir. 2004) (“[E]xpert testimony may be assigned talismanic significance in the eyes of lay jurors, and, therefore, the district courts must take care to weigh the value of such evidence against its potential to mislead or confuse.”).

Plaintiff’s tangled argument then claims that Dr. Marx should be allowed “to render an opinion that NPC was acting in bad faith” based on his rational “perceptions.” Pl’s Opp’n at 9-10. It is not clear whether plaintiff advocates that Dr. Marx offer this opinion as an expert or a fact witness, but it is precisely the testimony that the *Deutsch*, *Hogan*, and *Bessemer* courts excluded. *Deutsch*, 2011 WL 790702, at *26; *Hogan* Order at 7-8; *Bessemer* Opinion. This Court should exclude it as well.

B. Dr. Marx’s criticism of NPC’s clinical trials is inadmissible due to his lack of qualifications.

Plaintiff does not dispute that Dr. Marx lacks expertise in the highly specialized field of designing or conducting clinical trials involving cancer patients. Indeed, plaintiff does not dispute any of NPC’s arguments on the merits, but instead rehashes the decisions issued by other courts, most of which exclude Dr. Marx’s opinions on the issues NPC addresses. In fact, plaintiff concedes – as she must – that Dr. Marx was precluded from proffering his hindsight-based opinions on NPC’s clinical trial designs in the *Bessemer*, *Deutsch*, and *Hogan* cases. Pl’s Opp’n at 11; *see also Bessemer* Opinion; *Deutsch*, 2011 WL 790702, at *28 (“[T]here is no indication that he has ever been involved in designing or monitoring a clinical trial . . . he is simply not qualified to opine on the adequacy of clinical trials.”); *Hogan* Order at 11 (“Dr. Marx . . . would not . . . have the expertise to opine on the level of probability for developing a certain medical condition that pharmaceutical companies should tolerate before including a specialist to

monitor it during their [clinical] trials.”). This Court should likewise preclude Dr. Marx from criticizing NPC’s clinical trials.

Moreover, plaintiff’s reliance on the ruling in *Fussman* misses the mark because, although the court generally denied the parties’ *Daubert* motions (including NPC’s motion regarding Dr. Marx), the court allowed the parties to address admissibility issues at trial. *See Fussman v. Novartis Pharm. Corp.*, No. 1:06-CV-149 (M.D.N.C. Oct. 7, 2010) at 4-5 (“*Fussman Order*”) (Exhibit 2 to Vecchione Decl., ECF No. 74-2). During the *Fussman* trial, however, Dr. Marx did not testify regarding NPC’s clinical trials or whether any of the reports from the clinical trials described patients with BIONJ. Thus the admissibility of such proposed testimony by Dr. Marx was not even addressed during that trial.

II. Dr. Marx Cannot Reliably Opine That Certain Clinical Trial Patients Had BIONJ.

Plaintiff relies on the *Deutsch* court’s admission of Dr. Marx’s opinion that certain clinical trial patients had BIONJ to justify Dr. Marx’s complete failure to follow his own methodology when diagnosing BIONJ in his clinical practice. Pl’s Opp’n at 10. Even the *Deutsch* court agreed that “Dr. Marx may be overstating the results by concluding that these patients had ‘likely ONJ.’” *Deutsch*, 2011 WL 790702, at *27. Plaintiff contends that it is “unfair” to allow NPC experts to suggest BIONJ was not present in these patients while precluding plaintiff from offering expert testimony that these patients had BIONJ. Pl’s Opp’n at 10. Plaintiff’s fairness argument has no relevance to this Court’s *Daubert* determination. Plaintiff cannot defend Dr. Marx’s methodology in reaching this conclusion because he admitted that none of the relevant clinical trial patients’ medical records reflect exposed jawbone lasting more than eight weeks, which is the “key component” of the definition that he uses to determine whether his patients have BIONJ. *See NPC’s Opening Brief* at 6-7 (citing Dr. Marx’s deposition

testimony). The admission of an expert's rank speculation that deviates from the expert's professional practice flies in the face of *Daubert* standards, and the Court should exclude Dr. Marx's testimony on this point. *See* NPC's Opening Brief at 6-8.

III. Plaintiff Has Failed To Satisfy Her Burden Of Showing That Dr. Marx's Opinions About Dental Treatment Measures Satisfy The *Daubert* Standard.

Based on Dr. Marx's own admissions, he cannot testify that certain dental treatment measures are effective in *preventing* ONJ. *See* NPC's Opening Brief at 3-4. For example, he conceded that determining "whether any particular patient would have developed ONJ, but then didn't develop ONJ because of some sort of prebisphosphonate treatment dental exam, that's an *unknowable situation* at this point." *Id.* at 3 (quoting 5/26/09 Marx Dep. at 1367-68) (Exhibit 2 to NPC's Opening Brief, ECF No. 33-2) (emphasis added). In addition, Dr. Marx admitted that he has not published anything regarding what success (or lack of success) pretreatment dental evaluations have had with respect to his own patients, *id.* (citing 5/26/09 Marx Dep. at 1366), and that "*the jury is still out* in terms of controlled data on that issue," *id.* (quoting 5/26/09 Marx Dep. at 1367) (emphasis added).

Lacking any persuasive response to these important admissions, plaintiff tries to divert the Court's attention by focusing on a different issue – namely, that the Zometa[®] label, a position paper by the American Association of Oral and Maxillofacial Surgeons, and other documents give dental treatment recommendations that are similar to those of Dr. Marx. *See* Pl's Opp'n at 8. But plaintiff cannot deny that this area of inquiry is so new that nobody, including Dr. Marx, can present a scientifically reliable opinion that dental treatment measures *prevent* ONJ. The jury is still out, as Dr. Marx admitted, so his opinions on this issue should be excluded as speculation that is both confusing and not helpful to the jury. Fed. R. Evid. 702.

IV. *Daubert* Principles Preclude Dr. Marx From Testifying About Adverse Event Reports That He Admittedly Never Reviewed.

Based on Dr. Marx's report and deposition testimony, NPC established that Dr. Marx opines about numerous adverse event ("AE") reports that he admittedly never reviewed. *See* NPC's Opening Brief at 10-11. NPC simply contends that – whatever else Dr. Marx may be permitted to tell a jury about causation – he should be barred from testifying about these never-reviewed AE reports. Such testimony would violate basic principles of scientific reliability, especially given Dr. Marx's admission that he does not know which of the AE reports involved exposed jawbone, *see id.* (citing Dr. Marx's deposition testimony), and so which ones are actually ONJ.

Plaintiff's response is so muddled that it is difficult to determine her position on this issue. For example, she disputes the contention that Dr. Marx's causation opinion is based on AE reports that he has not reviewed, *see* Pl's Opp'n at 14, but she also quotes the paragraph in Dr. Marx's report referring to "almost 5000 reported cases of BIONJ," *id.* – and then contends that these AE reports "do not in any way constitute a significant factor upon which Dr. Marx relies in formulating his opinions on causation," *id.* at 15. If plaintiff concedes that Dr. Marx does not rely on these AE reports, then she should not object to this Court precluding him from testifying about them. On the other hand, if Dr. Marx relies – even if not to a "significant" extent – on AE reports that he has never reviewed, that is clearly contrary to the demanding scientific reliability standards established by *Daubert*. *See* NPC's Mem. at 11 (citing cases). Plaintiff's contention that Dr. Marx may testify about AE reports that he never reviewed does not pass the "straight face" test, let alone *Daubert*. *See Hogan* Order at 10 ("The jury will not have an expert recount the contents of documents that did not form the basis of his opinion.").

V. Dr. Marx's Biological Mechanism Opinion Is An Unproven Theory That Should Be Excluded Or, In The Alternative, Significantly Limited.

NPC asserted an expertise challenge and a reliability/methodology challenge to Dr. Marx's unproven theory regarding the biological mechanism by which he alleges bisphosphonate drugs cause ONJ. *See* NPC's Opening Brief at 11-13. Plaintiff has no persuasive rebuttal to either challenge. The fact that Dr. Marx has researched and published on ONJ and bisphosphonates, *see* Pl's Opp'n at 13, does not establish that Dr. Marx has sufficient expertise to address the highly complex, still-unresolved issue of biological mechanism.

In the alternative, if the Court decides that Dr. Marx is allowed to give mechanism testimony, the Court should significantly limit that testimony, as Judge Keenan did in lawsuits filed by Fosamax patients who allegedly developed ONJ. *See In re Fosamax Prods. Liab. Litig.*, 645 F. Supp. 2d 164 (S.D.N.Y. 2009). The *Fosamax* plaintiffs designated Dr. Marx as an expert witness to present mechanism testimony that is essentially the same as in this case. However, Judge Keenan significantly curtailed Dr. Marx's testimony, allowing him to testify about mechanism only if such testimony is "qualified in substance with a statement that it remains a theory that, subject to testing, may be proved or disproved." *Id.* at 198; *see also id.* at 183 (holding that expert witnesses testifying about "a biologically plausible mechanism" should not represent it "as a matter of scientific certainty" and must state that it "remains a theory that, subject to testing, may be proved or disproved"). If Dr. Marx is allowed to testify about biological mechanism here, this Court should impose the foregoing limitation on his testimony to ensure that jurors are not misled by Dr. Marx's unproven theory.

VI. Plaintiff Cannot Establish That Dr. Marx's Opinions Are Admissible By Relying On The MDL Court's Rulings Or The Inapplicable Law Of The Case Doctrine.

Perhaps recognizing that she has no way to establish that the opinions at issue here are

scientifically reliable, plaintiff cites an order issued by the MDL court about certain *case-specific* opinions that Dr. Marx presented. *See* Pl's Opp'n at 1 & Exhibit 2 to Pl's Opp'n, ECF Nos. 65, 65-2. But NPC has not re-asserted here the *Daubert* challenges that NPC presented to the MDL court regarding Dr. Marx's case-specific opinions (though NPC disagrees with those rulings).

Plaintiff also relies on the MDL court's order regarding Dr. Marx's "litigation-wide" (*i.e.*, non-case-specific) opinions, *see* Pl's Opp'n at 1 & Exhibit 1 to Pl's Opp'n, ECF Nos. 65, 65-1, falsely asserting that "Dr. Marx and his opinions were already approved by the MDL court in this case," Pl's Opp'n at 1. That misrepresents the MDL court's rulings. As plaintiff concedes, the MDL court specifically *declined* to rule on the admissibility of several opinions challenged by NPC here, namely "Dr. Marx's opinions concerning the alleged 'bad faith' misconduct of Novartis or his opinions concerning the clinical trials." Exhibit 1 to Pl's Opp'n at 4. Thus, the MDL court's short *Daubert* order regarding Dr. Marx's "litigation-wide" opinions does not provide any analysis that specifies which aspects of his general causation opinions it deemed admissible.

Although NPC disagrees with the MDL court's rulings to the extent that they denied certain *Daubert* challenges, NPC's *Daubert* motion now before this Court does not attempt to re-litigate any *Daubert* issue that was decided by the MDL court. For example, NPC's *Daubert* motion does not ask this Court to decide whether Dr. Marx's general causation opinion passes *Daubert* muster. Instead, given the limited and/or unclear scope of the MDL court's *Daubert* rulings as to certain issues, NPC has presented appropriate *Daubert* challenges to this Court.

In these circumstances, plaintiff's reliance on the "law of the case" doctrine, *see* Pl's Opp'n at 6, is misplaced. The law of the case doctrine is only applicable to "issues decided by final judgments." *Lovett v. Gen. Motors Corp.*, 975 F.2d 518, 522 (8th Cir. 1992); *see also*

Murphy v. FedEx Nat'l LTL, Inc., 618 F.3d 893, 905-06 (8th Cir. 2010) (holding that district court was not bound by law of the case doctrine to admit expert testimony at trial simply because it had relied on such testimony in denying summary judgment); *Gander Mountain Co. v. Cabela's, Inc.*, 540 F.3d 827, 830 (8th Cir. 2008) ("The doctrine applies to decisions made by appellate courts and final decisions made by district courts that have not been appealed. The doctrine does not apply to interlocutory orders.") (internal citations omitted). There is no "final judgment" implicated by NPC's present *Daubert* motion.

For the foregoing reasons and those set forth in NPC's opening memorandum, the Court should preclude Dr. Marx from testifying about the opinions addressed herein.

CONCLUSION

As shown above, plaintiff cannot satisfy her burden of establishing that Dr. Marx's opinions are admissible. Accordingly, the Court should preclude him from testifying about the opinions addressed herein.

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Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that I have on this 10th day of June 2011 served a true and correct copy of the foregoing Novartis Pharmaceuticals Corporation's Reply Suggestion in Support of Motion to Exclude Testimony of Plaintiff's Expert Robert Marx, D.D.S., by operation of the Court's Electronic Case Filing System:

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